IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

THIS DOCUMENT RELATES TO CIVIL ACTION NUMBER:

Cisson, et al. v. C. R. Bard, Inc. 2:11-cv-00195

MEMORANDUM OPINION AND ORDER
(Bard's Motion for Partial Summary Judgment Against Plaintiffs and Plaintiffs' Motion for Summary Judgment on Bard's Affirmative Defenses)

Pending before the court are Defendant C. R. Bard, Inc.'s ("Bard") Motion for Partial Summary Judgment Against Plaintiffs Donna Cisson and Dan Cisson [Docket 138] and Plaintiffs' Motion for Partial Summary Judgment on Bard's Affirmative Defenses and Brief in Support Thereof [Docket 144]. Responses and replies have been filed, and the motions are ripe for review. As set forth below, Bard's motion for partial summary judgment is **GRANTED in part** with respect to the plaintiffs' manufacturing defect, breach of express and implied warranty, and negligent inspection, marketing, packaging, and selling claims and **DENIED in part** with respect to the plaintiffs' failure to warn claim, and the plaintiffs' motion for partial summary judgment is **GRANTED in part** as to Bard's federal preemption defense (No. 26) and **DENIED in part** as to the remaining defenses.

I. Background

This case is one of several thousand assigned to me by the Judicial Panel on Multidistrict Litigation and one of four bellwether cases currently set for trial pursuant to Pretrial Order # 32.[1] These MDLs involve use of transvaginal surgical mesh to treat pelvic organ prolapse or stress urinary incontinence. The four bellwether cases involve implantation of one or more products, but only the pelvic organ prolapse products are at issue. In this case, Donna Cisson and her husband Dan Cisson (collectively referred to as "plaintiffs") allege that Ms. Cisson suffered injuries as a result of the Avaulta Plus Posterior Biosynthetic Support System ("Avaulta product") that was implanted in her. The Complaint alleges claims based on Ms. Cisson's injuries from the Avaulta product and Mr. Cisson's loss of consortium. The Complaint alleges the following causes of action: 1) negligence; 2) strict liability – design defect; 3) strict liability – manufacturing defect; 4) strict liability – failure to warn; 5) breach of express warranty; 6) breach of implied warranty; 7) loss of consortium; and 8) punitive damages. (*See* Compl. [Docket 1]). In the instant motions, Bard moves for summary judgment on several of these claims, and the plaintiffs move for summary judgment on several of Bard's affirmative defenses.[2]

II. Legal Standards

A. *Summary Judgment*

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the

[1] Originally, there was a fifth case, *Smith v. C. R. Bard*, No. 2:10-cv-01355, which was terminated on February 22, 2013 pursuant to a Stipulation of Dismissal/Order.

[2] Pursuant to the court's Pretrial Order # 72, *Daubert*-based dispositive motions, if any, pertaining to the other claims are to be filed at a later date.

evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds*, 490 U.S. 228 (1989).

B. *Choice of Law*

Under 28 U.S.C. § 1407, this court has authority to rule on pre-trial motions. In multidistrict litigation cases such as this, the choice-of-law for these pre-trial motions depends on whether they involve federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." *In re*

Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chicago, Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

This case was originally filed in the Northern District of Georgia. Therefore, I apply Georgia choice-of-law rules. Under Georgia law, the traditional *lex loci delicti* rule generally applies to tort actions. *Dowis v. Mud Slingers, Inc.*, 621 S.E.2d 413 (Ga. 2005). Under the *lex loci delicti* rule, the law of the place where the tort or wrong occurred governs the substantive rights of the parties. *See Federated Rural Elec. Ins. Exch. v. R.D. Moody & Assocs., Inc.*, 468 F.3d 1322, 1325 (11th Cir. 2006) (applying Georgia law). In addition, Georgia's choice-of-law system has an unusual characteristic: "the application of another jurisdiction's laws is limited to statutes and decisions construing those statutes." *Frank Briscoe Co., Inc. v. Georgia Sprinkler Co., Inc.*, 713 F.2d 1500, 1503 (11th Cir. 1983) (citing *Budget Rent-A-Car Corp. v. Fein*, 342 F.2d 509 (5th Cir. 1965) and *White v. Borders*, 123 S.E.2d 170 (Ga. Ct. App. 1961)). "When no statute is involved, Georgia courts apply the common law as developed in Georgia rather than foreign case law." *Id.*; *accord Kirkpatrick v. J.C. Bradford & Co.*, 827 F.2d 718, 725 n.6 (11th Cir. 1987) ("If a particular state does not have a controlling statute, however, the Georgia choice of law rule requires application of the common law as construed by the courts of Georgia); *Briggs & Stratton Corp. v. Royal Globe Ins. Co.*, 64 F. Supp. 2d 1340, 1343-44 (M.D. Ga. 1999)

(gathering post-*Frank Briscoe* cases from appellate courts of Georgia and concluding that rule from *Frank Briscoe* remains valid Georgia choice-of-law rule).

Here, the surgery to implant Ms. Cisson's Avaulta product was performed in Georgia and any alleged injuries occurred in Georgia. Accordingly, Georgia law applies to this case.

III. Bard's Motion for Summary Judgment

Bard argues that it is entitled to partial summary judgment because (1) the plaintiffs' manufacturing defect claims fail for lack of evidence; (2) the plaintiffs' failure to warn claims fail as a matter of law under the learned intermediary doctrine; (3) the plaintiffs' breach of warranty claims fail for lack of privity; and (4) the plaintiffs have not pursued their claims related to negligent inspection, marketing, packaging, and selling. I will address each of these issues below.

A. *Manufacturing Defect*

Bard contends that the plaintiffs have presented no evidence that the Avaulta product implanted in Ms. Cisson deviated from the underlying specifications for Avaulta products generally, and therefore the plaintiffs have presented no evidence of a manufacturing defect under Georgia law. The plaintiffs contend that they are entitled to proceed under their manufacturing defect or "inadvertent design" claim because they have produced evidence that the Avaulta product "failed to operate as intended." (Pls.' Resp. in Opp'n to Def. Bard's Mot. for Partial Summ. J. [Docket 202], at 4) [hereinafter Pls.' Resp.].

i. *Law*

The first issue for the court to resolve is the applicable law in Georgia on manufacturing defect claims. Georgia law recognizes "three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects." *Banks v. ICI*

Americas, Inc., 450 S.E.2d 671, 672 (Ga. 1994) (citing Maleski, Ga. Products Liability (2d ed.), § 5-1). Georgia's strict liability statute, in general, provides:

> The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

Ga. Code Ann. § 51-1-11(b)(1). In *Center Chemical Co. v. Parzini*, the Supreme Court of Georgia construed the phrase "not merchantable and reasonably suited to the use intended . . . to mean that the plaintiff must show that the manufacturer's product when sold by the manufacturer was defective." 218 S.E.2d 580, 582 (Ga. 1975). The Supreme Court of Georgia later clarified that "*Parzini* addressed manufacturing and packaging defects and did not recognize the existence of design defects, i.e., those cases where it was not possible to ascertain whether a product is 'defective' by simply comparing it to a properly manufactured item from the same product line." *Banks*, 450 S.E.2d at 672-73. In *Banks*, the Supreme Court of Georgia clarified the differences between a manufacturing defect and a design defect:

> Unlike a manufacturing defect case, wherein it is assumed that the design of the product is safe and had the product been manufactured in accordance with the design it would have been safe for consumer use, in a design defect case the entire product line may be called into question and there is typically no readily ascertainable external measure of defectiveness.

Id. at 673.[3] Judge Carnes of the Northern District of Georgia discussed this standard:

[3] The Georgia Supreme Court noted that "inadvertent design errors, which, as distinguished from conscious design choices, are treated in the same way as manufacturing defects." *Banks*, 450 S.E.2d at 673 n.2. The theory of "inadvertent design errors" appears in an extremely limited number of cases. *See id.*; *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1360 (N.D. Ga. 1999); *Trickett v. Adv. Neuromodulation Sys., Inc.*, 542 F. Supp. 2d 1338, 1345 (S.D. Ga. 2008). Each of these cases appears to treat a claim of inadvertent design defect as distinct from a claim of manufacturing defect, however, and simply explains that the *standard* under which the claims are to be analyzed is the same. The phrase "inadvertent design" never appears in either the plaintiffs' Master Complaint or Short-Form Complaint.

> A manufacturing defect is a defect that is measurable against a built-in objective standard or norm of proper manufacture . . . . [B]y definition, a manufacturing defect will always be identifiable as a deviation from some objective standard or a departure from the manufacturer's specifications established for the creation of the product.

Jones v. Amazing Prods., Inc., 231 F. Supp. 2d 1228, 1236 (N.D. Ga. 2002) (internal citation and quotation marks omitted). The plaintiffs' cited cases, including *Owens v. Gen. Motors Corp.*, 613 S.E.2d 651 (Ga. Ct. App. 2005) and *Williams v. Am. Med. Sys.*, 548 S.E.2d 371 (Ga. Ct. App. 2001), do not establish a different standard. Rather, the strict liability theory in both *Owens* and *Williams* was clearly that of manufacturing defect and not design defect such that the Court of Appeals of Georgia did not need to discuss the distinction between the two theories.[4] In sum, for a plaintiff to proceed on a manufacturing defect theory, he or she must establish "a deviation from some objective standard or a departure from the manufacturer's specifications established for the creation of the product." *Jones*, 231 F. Supp. 2d at 1236; *see also Graff v. Baja Marine Corp.*, 310 F. App'x 298, 305 (11th Cir. 2009).

ii. *Analysis*

Viewing the facts in the light most favorable to the plaintiffs, the plaintiffs have produced evidence that: (1) the Avaulta products are exposed to thermal and mechanical stresses during the manufacturing process, which cause the products to degrade; (2) the manufacturer of the polypropylene material used in the Avaulta products warned Bard that the material can degrade during thermal processing; (3) the pore sizes of the Avaulta products are smaller than the pore sizes that Bard represented to doctors and to its sales personnel; and (4) Bard knowingly designed the Avaulta products using material which it knew was expressly prohibited by the manufacturer for human implantation.

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[4] *See, e.g.*, *Owens*, 613 S.E.2d at 656 ("The case before us is not a design defect case, as Owens makes no contention that the *design* of the seat belt and air bag were [sic] defective, only that their *manufacturing* was defective.").

While some of the above evidence relates to the manufacturing process of the Avaulta products, the plaintiffs have produced no evidence to show that the Avaulta mesh that was ultimately implanted in Ms. Cisson deviated from "some objective standard" or from Bard's "specifications established for the creation of the product." *Jones*, 231 F. Supp. 2d at 1236. For example, the plaintiffs note that one of their experts testified "that the heat set process employed by Bard in the manufacture of the Avaulta devices subjects the material to extreme temperatures (290 ± 15° F), as well as mechanical forces during that heating process that significantly exceed the mesh's reported tensile strength." (Pls.' Resp. [Docket 202], at 5 n.5). Although this process is part of the manufacturing process of the Avaulta products, it would fall within the category of a *design* defect and not a *manufacturing* defect if the process, albeit faulty, were the same for all of these products. In contrast, if the expert had testified—for example—that the particular Avaulta product implanted in Ms. Cisson went through thermal and mechanical processes that caused the product to degrade and which deviated from Bard's processes for the same Avaulta products generally, then he may have provided evidence of a manufacturing defect.

Similarly, the alleged inadequate pore size and use of improper polypropylene material in the Avaulta products is a design issue—the plaintiffs do not allege that the Avaulta product implanted in Ms. Cisson had a different average pore size or was made out of different polypropylene material than Avaulta products generally. In sum, the plaintiffs have provided no evidence that the Avaulta product implanted in Ms. Cisson was not manufactured "in accordance with the design," *Banks*, 450 S.E.2d at 673, or that it deviated "from some objective standard" or departed "from the manufacturer's specifications established for the creation of the product."

Jones, 231 F. Supp. 2d at 1236.[5] Accordingly, Bard's motion for summary judgment on the manufacturing defect claim is **GRANTED**.

B. *Failure to Warn*

Bard contends that it is entitled to summary judgment on the plaintiffs' failure to warn claim predicated upon strict liability and negligence because of Georgia's learned intermediary doctrine. As stated by the Supreme Court of Georgia:

> Under the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities. Finally . . . under the learned intermediary doctrine, the manufacturer's warnings to the physician must be adequate or reasonable under the circumstances of the case.

McCombs v. Synthes (U.S.A.), 587 S.E.2d 594, 595 (Ga. 2003). The plaintiffs do not contest that Bard was required only to warn Ms. Cisson's treating physician, Dr. Brian Raybon, of the risks associated with the Avaulta product.

i. *Adequacy of the Warning*

"As a threshold issue, the Court should determine whether an adequate warning was given to [the plaintiff's] physician." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1363 (N.D. Ga. 1999); *see also Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010)

[5] The plaintiffs note that Bard uses the term "manufacturing defect" when referring to Dr. El-Ghannam's testimony on the thermal and mechanical processes used during the manufacture of the Avaulta products. (*See* Def. Bard's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Testimony of Ahmed El-Ghannam, Ph.D. [Docket 131], at 15-18). However, it is clear that Dr. El-Ghannam's opinion is that *all* Avaulta products go through this manufacturing process and therefore suffer from the same defect. (*See id.*). Accordingly, his opinions are related to design defects, notwithstanding any colloquial use of the term "manufacturing defect."

(applying Georgia law). "If the warning was adequate, the inquiry ends, and the plaintiff cannot recover." *Dietz*, 598 F.3d at 816 (citing *Singleton v. Airco, Inc.*, 314 S.E.2d 680, 682 (Ga. 1984)).

Bard argues that the Avaulta products' instructions for use ("IFU") warned of the specific risks and complications that Ms. Cisson complains of and that Dr. Raybon was fully aware of the relevant risks. The plaintiffs concede that Bard provides a list of potential complications in the IFU, but argues that Bard "unquestionably failed to warn of numerous known risks associated with its products." (Pls.' Resp. [Docket 202], at 11).

In *Zeigler v. CloWhite Co.*, the Court of Appeals of Georgia found that the trial court erred in granting the defendants' motion for summary judgment on the plaintiff's failure to warn claim where the defendant's product label failed to warn against dangers listed on a Material Safety Data Sheet ("MSDS") in its possession. 507 S.E.2d 182, 184-85 (Ga. Ct. App. 1998). The lemon-scent additive that CloWhite used for its lemon-scented bleach included a MSDS which warns that "the scent is incompatible with strong oxidizing agents." *Id.* at 184. CloWhite described its bleach as a "strong oxidizer." *Id.* The warning, however, was never provided. In this case, the plaintiffs provide evidence that Bard was in possession of a MSDS for the polypropylene resin used in the Avaulta products. The MSDS contained the following warning:

> MEDICAL APPLICATION CAUTION: Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

(Material Safety Data Sheet [Docket 200-1]).[6] The plaintiffs produced evidence that Bard never provided this warning to Dr. Raybon. Viewing the facts in the light most favorable to the plaintiffs, they have also produced evidence of other warnings that Bard never provided.

[6] Bard has not challenged the admissibility of the MSDS on any grounds in its summary judgment pleadings. The court is in receipt of a motion *in limine* as to the MSDS and will rule on that motion when it is ripe.

"Under Georgia law, a manufacturer breaches its duty to warn if it fails to 'adequately communicate the warning to the ultimate user or (2) fail[s] to provide an adequate warning of the product's potential risks.'" *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219 (11th Cir. 1999) (quoting *Thornton v. E.I. du Pont de Nemours & Co., Inc.*, 22 F.3d 284, 289 (11th Cir. 1994)). A warning may be insufficient or inadequate if it did not "provide a complete disclosure of the existence and extent of the risk involved." *Id; see also Sands v. Kawasaki Motors Corp.*, No. CV608-009, 2009 WL 3152859, at *5 (S.D. Ga. Sept. 30, 2009) (denying summary judgment because the evidence did not "preclude a jury from finding that Defendants failed to warn Plaintiff of both the extent of the danger and the severity of any injury"). Although Bard undisputedly warned of some potential adverse reactions in its IFU, I **FIND** that there is a genuine issue of material fact as to whether the warnings were adequate.[7]

ii. ***Whether the Inadequate Warning Proximately Caused the Alleged Injury***

Under Georgia law:

> If the warning is inadequate, or merely presumed to be, the plaintiff must demonstrate that the deficient warning proximately caused the alleged injury to prevail. Therefore, in cases where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that . . . the causal link is broken and the plaintiff cannot recover.

Dietz, 598 F.3d at 816 (internal citations and quotation marks omitted); *see also Baker v. Smith & Nephew Richards, Inc.*, No. 1:97-CV-1233, 1999 WL 1129650, at *7 (N.D. Ga. Sept. 30,

[7] Bard's Reply argues that the FDA cleared its Avaulta products, and therefore "approved the design, intended use, labeling, warnings, risks, and performance data for its Avaulta Plus and Solo Systems." (Def. Bard's Reply Mem. of Law in Supp. of its Mot. for Partial Summ. J. Against Pls. Donna Cisson & Dan Cisson [Docket 235], at 10). Bard offers as evidence of the adequacy of its warnings the fact that the FDA never indicated that Bard failed to adequately warn of the risks or potential complications. Notwithstanding the FDA's processes, the plaintiffs have presented sufficient evidence to create a genuine issue of material fact as to the adequacy of Bard's warnings.

1999). Bard argues that Dr. Raybon had actual knowledge of all of the potential risks and that the plaintiffs "cannot establish that Dr. Raybon would not have implanted the Avaulta had he received additional information because Dr. Raybon does not consider such information as part of his practice." (Def. Bard's Mem. of Law in Supp. of Mot. for Partial Summ. J. Against Pls. Donna Cisson & Dan Cisson [Docket 139], at 17-18). The plaintiffs have provided evidence, through Dr. Raybon's testimony, that Bard failed to warn Dr. Raybon of certain risks and that knowledge of such risks would have changed Dr. Raybon's decision to implant the Avaulta product into Ms. Cisson. In sum, the plaintiffs have provided sufficient evidence to create a genuine issue of material fact as to whether Dr. Raybon would have implanted the Avaulta Plus product in Ms. Cisson had he known of the information that the plaintiffs contend should have been provided to him. Accordingly, I **FIND** that there is a genuine issue of material fact as to whether the allegedly inadequate warning proximately caused the injury to Ms. Cisson. Because I find that there is a genuine issue of material fact as to (1) whether the warnings were adequate and (2) whether the allegedly inadequate warnings proximately caused Ms. Cisson's injuries, Bard's motion for summary judgment on the failure to warn claim is **DENIED**.

C. ***Express and Implied Breach of Warranty***

Bard contends that the plaintiffs' claims for breach of express and implied warranty fail for lack of privity between the plaintiffs and Bard. The plaintiffs fail to address this argument in their response and have not offered any evidence to support these claims. Under Georgia law, there must be "privity between the parties where a plaintiff-purchaser of an article has been injured because of its alleged defectiveness and brings an action based on warranty." *Gowen v. Cady*, 376 S.E.2d 390, 393 (Ga. Ct. App. 1988). In *Andrews v. RAM Medical, Inc.*, the Middle District of Georgia held, pursuant to Georgia law, that: "Plaintiffs cannot establish privity with

[the defendant manufacturer] because the surgical mesh was not sold directly to Plaintiffs. Therefore, any claims for breach of express or implied warranty must fail under Georgia law." No. 7:11-CV-147 (HL), 2012 WL 1358495, at *3 (M.D. Ga. Apr. 19, 2012); *see also Baker*, 1999 WL 1129650, at *8 (holding that "the recipient of an internally implanted medical device does not have standing to bring a claim for breach of implied warranty" where the device was sold to hospitals and not the plaintiffs directly). Accordingly, Bard's motion for summary judgment on the express and implied breach of warranty claims is **GRANTED**.

D. ***Negligent Inspection, Marketing, Packaging, and Selling***

Bard contends that the plaintiffs' claims for negligent inspection, marketing, packaging, and selling fail for lack of evidence to the extent that they are distinct from the plaintiffs' manufacturing, design, and warnings claims. (*See* Master Compl., Case No. 2:10-md-02187 [Docket 351-1], ¶¶ 64(d)-(e)). The plaintiffs fail to address this argument in their response and have not offered any evidence to support these claims. Accordingly, Bard's motion for summary judgment on the negligent inspection, marketing, packaging and selling claims is **GRANTED**.

IV. The Plaintiffs' Motion for Summary Judgment

The plaintiffs argue that they are entitled to partial summary judgment on Bard's affirmative defenses related to (1) contributory negligence; (2) comparative negligence; (3) assumption of risk; (4) mitigation of damages; and (5) federal preemption. I will address each of these issues below.

A. ***Contributory Negligence***

Bard has voluntarily withdrawn affirmative defenses 6 and 12, which relate to contributory negligence; however; Bard has not withdrawn affirmative defense 14 "to the extent it relates to comparative negligence/fault." (Def. Bard's Mem. of Law in Opp'n to Pls.' Mot. for

Partial Summ. J. on Def.'s Affirmative Defenses [Docket 203], at 1 n.2) [hereinafter Bard's Resp.]. Accordingly, the plaintiffs' motion for summary judgment on Bard's contributory negligence defenses is **DENIED as moot**. I will consider affirmative defense 14 only to the extent that it relates to comparative negligence.

B. *Comparative Negligence*

Georgia recognizes comparative negligence by statute, which states:

> Where an action is brought against one or more persons for injury to person or property and the plaintiff is to some degree responsible for the injury or damages claimed, the trier of fact, in its determination of the total amount of damages to be awarded, if any, shall determine the percentage of fault of the plaintiff and the judge shall reduce the amount of damages otherwise awarded to the plaintiff in proportion to his or her percentage of fault.

Ga. Code Ann. § 51-12-33(a). Georgia case law clarifies that under this doctrine:

> [W]here the negligence of the plaintiff joins with the negligence of the defendant in proximately causing the plaintiff's injuries, the plaintiff will be precluded from recovering against the defendant, if the negligence of the plaintiff is equal to or greater than that of the defendant, *or*, if the negligence of the plaintiff is less than that of the defendant, the plaintiff's recovery of damages will be reduced in proportion to his or her negligence.

Weston v. Dun Transp., 695 S.E.2d 279, 282 (Ga. Ct. App. 2010) (citing *Garrett v. Nationsbank, N.A. (South)*, 491 S.E.2d 158, 163 (Ga. Ct. App. 1997)). The underlying policy is that "[i]t is axiomatic that all persons are required to exercise ordinary care for their own wellbeing." *McMullen v. Vaughan*, 227 S.E.2d 440, 442 (Ga. Ct. App. 1976).

The plaintiffs argue that "there is a dearth of evidence that would establish or even suggest that Mrs. Cisson acted negligent[ly] in any way." (Pls.' Mot. for Partial Summ. J. on Def. Bard's Affirmative Defenses & Brief in Support Thereof [Docket 144], at 7) [hereinafter Pls.' Mot.]. Bard has provided some evidence that (1) Ms. Cisson failed to take efforts to reduce her weight before and after her surgery, which may have contributed to her conditions; (2) Ms.

Cisson failed to use Estrace cream as instructed by her physician; and (3) Ms. Cisson failed to seek a second opinion or attempt a less invasive treatment before proceeding with surgery. Viewing this evidence in the light most favorable to Bard, I **FIND** that Bard has set forth more than a "scintilla of evidence" to support its affirmative defense on comparative negligence, and the plaintiffs' motion for summary judgment on this issue is **DENIED**.

C. *Assumption of Risk*

Under Georgia law:

> The affirmative defense of assumption of the risk bars a plaintiff from recovering on a negligence claim if it is established that he without coercion of circumstances, chooses a course of action with full knowledge of its danger and while exercising a free choice as to whether to engage in the act or not. In Georgia, a defendant asserting an assumption of the risk defense must establish that the plaintiff (1) had actual knowledge of the danger; (2) understood and appreciated the risks associated with such danger; and (3) voluntarily exposed himself to those risks.

Vaughn v. Pleasent, 471 S.E.2d 866, 868 (Ga. 1996) (internal footnotes and quotation marks omitted). The plaintiffs argue that Bard cannot point to any evidence that Ms. Cisson assumed the risk of having a defective product implanted. The plaintiffs further argue that "[i]n order to prevail on an assumption of risk defense, Bard must concede the defectiveness of its design, and then establish that these Plaintiffs knowingly and voluntarily assumed that risk." (Pls.' Reply in Supp. of their Mot. for Partial Summ. J. on Defs.' Affirmative Defenses [Docket 232], at 7) [hereinafter Pls.' Reply].

Whether the Avaulta products are defective has not yet been determined.[8] Bard is certainly entitled to rely on alternative arguments. In other words, if the court or jury found that the Avaulta product was not defective, the inquiry would end; however, if the court or jury found that the Avaulta product was defective, it would then proceed with the inquiry as to whether Ms.

[8] The deadline for *Daubert* based dispositive motions has not yet passed, and from several of Bard's filings, it appears that Bard intends to challenge the issue of design defect at that time.

Cisson understood and assumed the risk of having the defective Avaulta product implanted in her.

Bard presents evidence that Ms. Cisson signed consent forms to implant the Avaulta product. The plaintiffs have cited no binding authority to support their argument that the consent forms would be inadmissible in this case. The plaintiffs additionally argue that the consent form "has absolutely no bearing on any issue in this product liability action, and certainly does not represent the sort of voluntary acceptance of risks of defects within the Avaulta product that would support such affirmative defense." (Pls.' Reply [Docket 232], at 6). However, Bard has provided evidence that the consent forms disclosed the risks of implanting the Avaulta product and that Dr. Raybon knew and understood the risks and communicated them to Ms. Cisson. Accordingly, even if the court or jury found that the Avaulta product was in fact defective, there would be a genuine issue of material fact as to whether Ms. Cisson knew of and understood the defects and nonetheless consented. "[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). I **FIND** that there is a genuine issue of material fact as to whether, even assuming the Avaulta product is defective, Ms. Cisson nonetheless assumed the risks, and the plaintiffs' motion for summary judgment on the assumption of risk defense is **DENIED**.

D. *Mitigation of Damages*

Georgia law requires a plaintiff to mitigate his or her damages: "When a person is injured by the negligence of another, he must mitigate his damages as far as practicable by the use of ordinary care and diligence." Ga. Code Ann. § 51-12-11; *see Butler v. Anderson*, 295 S.E.2d 216, 217 (Ga. Ct. App. 1982). The plaintiffs argue that "Bard can cite no evidence that Mrs.

Cisson failed to take reasonably diligent steps to mitigate her damages upon sustaining injuries attributable to Bard's defective product." (Pls.' Mot. [Docket 144], at 8). However, Bard has produced evidence that Ms. Cisson failed to use the Estrace cream despite physician instructions, even though she saw improvement while using it. (*See* Miklos Dep. [Docket 103-2], at 164:3-164:7). Accordingly, I **FIND** that there is a genuine issue of material fact as to whether Ms. Cisson mitigated her damages, and the plaintiffs' motion for summary judgment on this issue is **DENIED**.

E. *Federal Preemption*

The plaintiffs argue that their state law claims are not barred by federal preemption under Supreme Court law, and therefore they are entitled to summary judgment as to the affirmative defense of federal preemption. Bard appears to concede that the plaintiffs' state law claims are not expressly preempted under *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), but argues that they are impliedly preempted under *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court stated:

> [I]t is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

531 U.S. at 352-53; *see also Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (holding that "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA-that is, when the state claim would not exist if the FDCA did not exist").

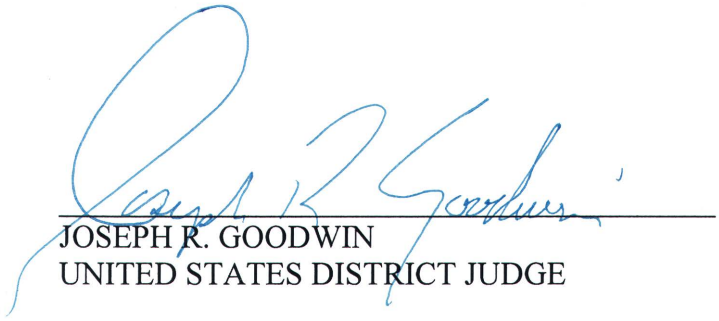
Accordingly, the state law claims themselves may not be *based on* fraud against the FDA, but evidence as to whether Bard failed to provide certain information to the FDA may nonetheless be relevant to the state law claims. *See In re Medtronic, Inc, Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006); *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002). Bard notes that its "interaction with the FDA is one of the points of contention in this case" and therefore "genuine issues of fact preclude summary judgment on this affirmative defense." (Bard's Resp. [Docket 203], at 15). The plaintiffs argue that they "have not asserted, and do not intend to assert, any claim for 'fraud on the FDA,' whether 'latent' or otherwise." (Pls.' Reply [Docket 232], at 8). I agree that the plaintiffs have not asserted any such claim. Accordingly, as a matter of law, the plaintiffs are entitled to summary judgment on the issue of federal preemption, and their motion for summary judgment on this issue is **GRANTED**.

V. Conclusion

For the reasons discussed above, it is **ORDERED** that Bard's motion for partial summary judgment [Docket 138] is **GRANTED in part** with respect to the plaintiffs' manufacturing defect, breach of express and implied warranty, and negligent inspection, marketing, packaging, and selling claims and **DENIED in part** with respect to the plaintiffs' failure to warn claim. It is further **ORDERED** that the plaintiffs' motion for partial summary judgment [Docket 144] is **GRANTED in part** as to Bard's federal preemption defense (No. 26) and **DENIED in part** as to the remaining defenses.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: June 4, 2013



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE